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EXAMINER	
KEYS, ROSALYND ANN	
ART UNIT	PAPER NUMBER
1621	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,049	LIANG ET AL.	
	Examiner	Art Unit	
	Rosalynd Keys	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,6,8,11-14 and 16-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2,3,6,8,11-14 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/22/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 2, 3, 6, 8, 11-14 and 16-18 are pending.

Claims 2, 3, 6, 8, 11-14 and 16-18 are rejected.

Claims 1, 4, 5, 7, 9, 10 and 15 have been cancelled.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Currently it appears that the prevention of diseases related to diabetes such as hypertension and obesity is through lifestyle changes see for example http://www.webmd.com/hypertension-high-blood-pressure/tc/high-blood-pressure-hypertension-prevention (dated April 27, 2009) and http://www.health.state.ny.us/prevention/obesity/ (dated November 2008). Thus, since none of the examples in Applicants specification actually show prevention of diseases related to diabetes, the Applicants have not shown how to use the invention of claims

16-18, especially in light of current knowledge on the prevention of diseases related to diabetes such as hypertension and obesity.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 2, 3, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dittrich et al. (Phytochemistry, Vol. 11, 1971, pp. 245-250) in view of Sultana et al. (Phytochemistry, Vol. 50, 1999, pp. 1249-1253) or Page et al. (US 6,002,025) and Liu (US 5,969,165).

Dittrich et al. teach that the compound 5-O-methyl-myo-inositol (sequoyitol) is found in the Taxaceae class and family of plants, but Dittrich et al. do not disclose a method of extracting said compound from said plants.

The steps and solvents disclosed in claims 2, 3, 6, and 8 are well known and are taught for example by Sultana et al. (see section 3.2 on pages 1251 and 1252), Page et al. (see column 7, line 48 to column 9, line 2) and Liu (see column 1, line 18 to column 6, line 43). Liu additionally teaches the use of a macroporous resin (see example 1, in particular column 5, lines 62-66). Liu further teaches that his method allows for large industrial scale production (see column 1, lines 41-57).

One having ordinary skill in the art at the time the invention was made would have found it obvious to extract the compound 5-O-methyl-myo-inositol (sequoyitol) from the Taxaceae class and family of plants as disclosed in Dittrich et al. by using well known steps and solvents such as those taught by Sultana et al., Page et al. and Liu

Sultana et al. and Page et al. do not disclose that their columns are macroporous. However, Liu, which teaches similar isolation and purification steps as Sultana et al. and Page et al. teach the use of a macroporous resin and further teaches

that his process allows the isolation to be conducted via a large industrial scale production. One having ordinary skill in the art at the time the invention was made would have found it obvious to utilize a column having the pore size necessary for obtaining the desired separation based upon the scale of production desired. The claims would have been further obvious because "a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." KSR International Co. v. Teleflex Inc., 550 U.S.___, 82 USPQ2d 1385, 1395-97 (2007).

Further, where the process steps of Sultana et al., Page et al. (US 6,002,025) and Liu differ from the instant claims in the order in which the steps are performed the instant claims are still considered to be prima facie obvious because the time at which a particular step is performed is simply a matter of operator preference, especially since the same result is obtained regardless of when the step occurs. See Ex parte Rubin, 128 USPQ 440 (Bd. App. 1959) (Prior art reference disclosing a process of making a laminated sheet wherein a base sheet is first coated with a metallic film and thereafter impregnated with a thermosetting material was held to render prima facie obvious claims directed to a process of making a laminated sheet by reversing the order of the prior art process steps.). See also In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.).

Dittrich et al. in view of Sultana et al. or Page et al. and Liu do not teach obtaining more than 90% if 5-O-methyl-myo-inositol. However, one having ordinary skill in the art would have found it obvious to perform the extraction steps of Sultana et al. or Page et al. and Liu until the desired amount of 5-O-methyl-myo-inositol was obtained.

8. Claims 11-14 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostlund et al. (US 5,550,166) in view of Dittrich et al. (Phytochemistry, Vol. 11, 1971, pp. 245-250) and Oberley Free Radic Biol Med. 1988;5(2):113-24 (abstract) [online], [retrieved 2008-05-11]. Retrieved from the internet <URL: http://www.ncbi.nlm.nih.gov/pubmed/3075947.

Ostlund et al. teach the compound pinitol, compositions containing pinitol and its use in the treatment of diabetes (see entire disclosure, in particular column 1, lines 12 to 30 and column 3, line 11 to column 5, line 52). Pinitol is a stereoisomer of the claimed sequoyitol (see page 246 of Dittrich et al.). One having ordinary skill in the art at the time the invention was made would have found it obvious to utilize 5-O-methyl-myo-inositol (sequoyitol) in a composition for the treatment of diabetes, as taught by Ostlund, because compounds which are generally of sufficiently close structural similarity there is a presumed expectation that such compounds possess similar properties. *In re Wilder,* 563 F.2d 457, 195 USPQ 426 (CCPA 1977). See also *In re May*, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978) (stereoisomers prima facie obvious).

Ostlund et al. in view of Dittrich et al. do not teach the improvement in the metabolism of free radicals.

Oberley teaches that not only are oxygen radicals involved in the cause of diabetes, they also appear to play a role in some of the complications seen in long-term treatment of diabetes.

One having ordinary skill in the art at the time the invention was made would reasonably expect that based upon the teachings of Oberley, that treatment of diabetes and its complications in the manner taught by Ostlund et al. in view of Dittrich et al. would also involve treatment of free radicals which according to Oberley is a cause of diabetes.

Response to Arguments

Rejection of claims 2, 3, 6, and 8 under 35 U.S.C. 103(a) as being unpatentable over Dittrich et al. (Phytochemistry, Vol. 11, 1971, pp. 245-250) in view of Sultana et al. (Phytochemistry, Vol. 50, 1999, pp. 1249-1253) or Page et al. (US 6,002,025) and Liu (US 5,969,165)

9. Applicant's arguments filed January 22, 2009 have been fully considered but they are not persuasive.

The Applicants argue that there is no indication that Taxaceae or Taxus baccata contain useful, extractable amounts of sequoyitol, or that this class can serve as a source of the same.

This argument is not persuasive because although the amount of sequoyitol is not disclosed Dittrich et al. clearly teach in the first paragraph on page 248 that sequoyitol is present in plants of the Taxaceae family “As seen in Table 1 sequoyitol

and D-pinitol are present in all classes of gynosperms except the Chlamydospermae…." Thus, one having ordinary skill in the art at the time the invention was made would have a reasonable expectation that plants of the Taxaceae family are a suitable source for sequoyitol based upon this teaching of Dittrich et al. Further, Dittrich et al. teach hot water extracts of the species listed in Table 1, which includes plants of the Taxaceae family (see the first full paragraph on page 246). Thus, based upon this teaching of Dittrich et al. one having ordinary skill in the art would have a reasonable expectation that sequoyitol could be extracted from Taxaceae plants.

The Applicants argue that Applicants used macroporous resin, but Sultana used silica gel column chromatograph and that there is no suggestion to change the procedure of Sultana.

This argument is not persuasive because the Examiner already recognized that Sultana did not use macroporous resins, thus Liu was applied for this teaching and Liu provides the motivation for using a macroporous resin, i.e., his process allows the isolation to be conducted via a large industrial scale production.

The Applicants argue that none of Sultana, Dittrich, Page' or Liu suggest that Taxaceae would be a good source of sequoyitol.

This argument is not persuasive because as pointed out about although the amount of sequoyitol is not disclosed, Dittrich et al. clearly teach in the first paragraph on page 248 that sequoyitol is present in plants of the Taxaceae family and therefore the skilled artisan would have a reasonable expectation that plants of the Taxaceae family are a good source for sequoyitol.

Applicants argue that the method of isolation of sequoyitol is different from the method Page' uses to extract taxanes because the Applicants used macroporous chromatography whereas page used distribution chromatography.

This argument is not persuasive because Page' is not used as a reference for the type of chromatography that is used but rather to show that it is known to obtain taxanes from the bark and needles of different Taxus species by using steps such as extraction, chromatography and crystallization and that solvents such as methanol and ethanol were known for use in extraction.

Applicants arguments with regard to Liu using a Dowex strong acid cation ion exchange resin to separate non-polar taxanes is not persuasive because the claims only require that a macroporous resin column be used. The claims do not limit the type of macroporous resin. Further, Liu is used to show that by using a macroporous resin one can adapt a small scale production into a large scale production if desired.

The Examiner maintains that the Applicants have simply used known extraction steps and solvents to extract 5-O-methyl-myo-inositol from a plant family, i.e., Taxus spp. in which it was already known to exist. Thus, the Applicants method of extraction is prima facie obvious. The rejection is maintained.

Rejection of claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ostlund et al. (US 5,550,166) in view of Dittrich et al. (Phytochemistry, Vol. 11, 1971, pp. 245-250) and Oberley Free Radic Biol Med. 1988;5(2):113-24 (abstract)

[online], [retrieved 2008-05-11]. Retrieved from the internet <URL:

http://www.ncbi.nlm.nih.gov/pubmed/3075947

10. Applicant's arguments filed January 22, 2009 have been fully considered but they are not persuasive.

The fact that compounds that are similar in structure may possess different properties does not negate the fact that such compounds may also possess similar properties.

The fact that Davis showed that pinitol did not increase insulin sensitivity in obese individuals with mild type 2 diabetes, does not negate the teaching in Ostlund et al. that pinitol is effective in lowering blood glucose levels.

The fact that Campbell shows that pinitol supplementation does not affect insulin-mediated glucose metabolism in *older people* does not negate the teaching in Ostlund et al. that pinitol and its derivatives and metabolites thereof are useful for improving plasma lipid and lipoprotein levels by reducing triglycerides or low density lipoprotein cholesterol or by increasing high density lipoprotein cholesterol.

Plourde is directed to synthesis of a glucosaminyl-inositol-1,2-cyclic phosphate, which was designed to resemble structurally the recently reported inositol glycans. There is no teaching that inositol derivatives needed to be in the disaccharide form to have insulin-like effects.

For the above reasons this rejection is maintained.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosalynd Keys whose telephone number is (571)272-0639. The examiner can normally be reached on M & T 5:30 am-7 am & 9:30 am-4:30 pm: W-F 8:00 am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rosalynd Keys/
Primary Examiner, Art Unit 1621

April 27, 2009